UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GAMBRO RENAL PRODUCTS, INC.,	:	CIVIL ACTION NO.
Plaintiff,	:	
V.	:	
NxSTAGE MEDICAL, INC.,	:	
Defendant.	:	

COMPLAINT AND JURY DEMAND

Plaintiff Gambro Renal Products, Inc., as and for its Complaint against defendant NxStage Medical, Inc., alleges as follows:

THE PARTIES

1. Plaintiff Gambro Renal Products, Inc. ("Gambro") is a Colorado corporation with its principal place of business in Lakewood, Colorado.

2. Defendant NxStage Medical, Inc. ("NxStage") is a Delaware corporation with its principal place of business in Lawrence, Massachusetts.

JURISDICTION AND VENUE

3. This action arises under the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, the Massachusetts Consumer Protection Act, Mass. G.L. c. 93A, and the common law.

4. This Court has subject matter jurisdiction over this action under 15 U.S.C. §§ 1121 and 1125 and 28 U.S.C. §§ 1331 on the grounds that this civil action arises under the laws of the United States.

5. This Court also has subject matter jurisdiction over the state law claims under 28

U.S.C. § 1332(a) on the grounds that the matter in controversy exceeds the sum of $75,000, exclusive of interest and costs, and is between citizens of different states. Additionally, the Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367 on the grounds they are so related to the federal claims that they form part of the same case or controversy.

6. This Court has personal jurisdiction over NxStage because its principal place of business is in this district, it does business in this district, and the acts complained of arose and occurred in part in this district.

7. Venue is proper in this district because NxStage resides in this district.

FACTS COMMON TO ALL CLAIMS

8. Gambro brings this action to enjoin NxStage from continuing, and to recover damages resulting from, NxStage's pervasive and systematic marketing plan of making false statements or misleading descriptions about the nature, characteristics, and qualities of NxStage's and Gambro's competing continuous renal replacement therapy machines in commercial advertising and promotional activity targeting intensive care units at hospitals throughout the United States.

A. CRRT Hemodialysis Devices

1. General Background

9. In the mid-1960s, Gambro's parent corporation in Sweden developed and began selling some of the world's first artificial kidneys and hemodialysis devices that performed the process of removing waste products and excess water from patients' blood as a substitute for malfunctioning or nonfunctioning human kidneys.

10. Basically, a hemodialysis device withdraws blood from patients through plastic tubes known as bloodlines into a dialyzer, a filter with thousands of small tubular membranes that treat the blood outside the body by removing waste products and excess water. The cleansed blood is then returned to the patient while the removed waste products and excess water are discarded in the drainage fluid (the "effluent").

11. This type of dialysis treatment is most commonly prescribed for patients with irreversible kidney failure known as end-stage renal disease ("ESRD"), which typically develops slowly over many years. Although these patients frequently have many chronic illnesses, such as cardiovascular disease and diabetes, in addition to their irreversible renal failure, they are usually stable enough to be treated intermittently at an outpatient hemodialysis clinic or at home for several hours during each of three or more sessions per week.

12. Another type of renal disease is acute kidney injury ("AKI"), a form of severe but potentially reversible kidney failure that usually develops very abruptly within a few days, frequently after major surgery or in association with a severe infection such as pneumonia. As opposed to ESRD patients treated with outpatient hemodialysis, these critically ill AKI patients are typically treated in a hospital intensive care unit since they are particularly unstable from a blood pressure perspective. Moreover, because large volumes of fluid are frequently administered to such patients to support their blood pressure and because their acutely damaged kidneys cannot discard the fluid, they are at risk of developing severe fluid overload and becoming bloated.

13. Intermittent hemodialysis, as described above, is generally not appropriate for critically ill AKI patients because it frequently destabilizes a patient's blood pressure even further. Instead, these patients are prescribed an alternative hemodialysis technique called

continuous renal replacement therapy ("CRRT"). As opposed to intermittent hemodialysis, CRRT is prescribed for treatment around the clock.

14. As indicated above, a basic requirement of any hemodialysis therapy is the removal of excess fluid that has accumulated due to kidney failure. The two basic approaches employed by hemodialysis devices to control the accuracy of fluid removal are volumetric fluid balancing and gravimetric fluid balancing. Machines providing intermittent hemodialysis employ volumetric fluid balancing.

15. For critically ill AKI patients, however, gravimetric fluid balancing was incorporated into devices in the 1990s specifically for CRRT out of concerns about the inability of volumetric fluid balancing to provide sufficiently accurate fluid removal while at the same time maintaining blood pressure stability. As opposed to a volumetric device, a gravimetric device (also called a scale-based device) continuously weighs fluids on scales and monitors fluids that are exchanged between the patient and the machine during CRRT treatment.

16. Data collected by this continuous weighing are provided to the device's software, which can in turn modulate various fluid pump speeds to correct and compensate for any differences between the clinician's prescription and the actual fluid administered or removed during treatment. The fundamental ability to monitor, second by second, all fluid weights and, therefore, volumes provides gravimetric devices with the ability to achieve greater fluid accuracy than volumetric devices. Primarily for this reason, gravimetric devices have largely supplanted volumetric devices as the most common and widely applied machines used in CRRT treatment of critically ill AKI patients throughout the world.

2. Gambro's Prisma and Prismaflex Machines

17. In 1997, Gambro's predecessor company first offered in the United States the "Prisma" machine, one of the first gravimetric renal replacement devices developed specifically for CRRT. Eight years later in 2005, Gambro introduced in the United States the "Prismaflex" machine, the company's second generation gravimetric CRRT device. In addition to hemodialysis in which the fluid exchanged is dialysate, Prisma and Prismaflex provide the capability to perform hemofiltration in which the exchanged fluid is called replacement fluid. Another hemodialysis modality provided by Prisma and Prismaflex is hemodiafiltration, a combination of hemodialysis and hemofiltration in which both dialysate and replacement fluids are used. Dialysate and replacement fluids, which treat the patient's blood in different ways, contain sugars and salts and are manufactured to be similar to the composition of human plasma water.

18. Besides Gambro, the only other manufacturer of a gravimetric renal replacement device used currently in the United States for AKI patients is B. Braun. B. Braun has cited the Prisma machine as a predicate device in its submission under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the "Act") to the United States Food & Drug Administration ("FDA") for clearance of its gravimetric CRRT device. While other gravimetric CRRT devices have been cleared by the FDA over the past 15 years, they are no longer marketed in the United States.

3. NxStage's System One Machine

19. Although gravimetric devices are much more commonly used for CRRT both in the United States and elsewhere, volumetric devices are also used in some hospital intensive care units for CRRT in the United States. One such volumetric device is NxStage's System One.

20. NxStage began selling its System One device approximately in or around 2002, but most of its sales have been for ESRD patients who prefer intermittent hemodialysis in the home setting rather than at a clinic. The primary purpose in NxStage's development of System One was to create a device that would address the needs of ESRD patients rather than those of critically ill AKI patients. The System One device sold to hospital intensive care units for CRRT is essentially the same as the one sold for intermittent hemodialysis for home use, except the CRRT device has an additional display module. As explained above, the NxStage System One's volumetric control system does not weigh exchanged fluid at all and, therefore, cannot make continuous changes in fluid exchange rates based on potential differences between prescribed (*i.e.*, programmed) volumes and actual fluid volumes.

4. Capabilities

21. CRRT incorporates a number of different therapies: Slow Continuous Ultrafiltration ("SCUF"), Continuous Veno-Venous Hemofiltration ("CVVH"), Continuous Veno-Venous Hemodialysis ("CVVHD"), and Continuous Veno-Venous Hemodiafiltration ("CVVHDF"). CVVHDF has become the most commonly prescribed CRRT modality in the United States.

22. Gambro's Prisma and Prismaflex offer all four options.

23. NxStage's System One performs SCUF, CVVH, and CVVHD but not CVVHDF.

B. NxStage's Advertising and Promotional Misrepresentations

24. NxStage is in commercial competition with Gambro with respect to the sale of CRRT devices to hospitals.

25. For the past several years, through its marketing plans and sales training programs emanating from or approved at its headquarters in Lawrence, Massachusetts, NxStage has

advertised, marketed, and promoted its System One to hospitals throughout the United States in a variety of ways, including in its brochures, on its website, in medical periodicals, at national and international medical and industry conferences attended by hospital physicians and staff, at national continuing medical education programs attended by hospital physicians and staff, and in meetings with hospital physicians and staff.

26. In such advertisements and marketing and promotional activities, NxStage has systematically and as part of its overall marketing plan falsely described or misrepresented or made misleading descriptions or representations about the nature, characteristics, and qualities of its System One device, of Gambro's Prisma and Prismaflex devices, and of System One as compared to Prisma or Prismaflex.

27. Because there are only two manufacturers of gravimetric CRRT machines marketing and selling to customers in the United States, whenever NxStage has made statements about gravimetric or scaled-based machines in general, it has intended its references to mean or include Gambro's Prisma or Prismaflex machine, and customers and potential customers have understood such statements to refer to Gambro's Prisma or Prismaflex machine.

28. Examples of such false or misleading advertisements and marketing and promotional activities disseminated widely throughout the United States market for CRRT machines are described below. In general, NxStage's false or misleading advertising and promotions have included statements about System One's and/or Prisma's or Prismaflex's fluid accuracy, safety, anticoagulation requirements, and nurse workload and false claims that System One has capabilities equivalent to CVVHDF therapy.

1. Fluid Accuracy and Safety of System One and Prismaflex

29. Fluid accuracy is a measure of the degree to which a CRRT device performs as programmed and actually provides to the patient the therapy prescribed by the physician from a fluid removal perspective. Thus, an important selling feature of a CRRT device is its fluid accuracy.

30. On September 17, 2009, NxStage stated orally and in writing during its presentation at the University of Alabama's CRRT Academy that the fluid accuracy specification for System One is "the greater of 300 ml/12 hours or 3% of the therapy fluid exchange volume." On February 23, 2011, Mike Schrader, NxStage's Vice President of Critical Care, repeated that statement at the 2011 International CRRT Conference in San Diego. These statements are consistent with the fluid accuracy specification of System One, as reported in its User's Guide, which represents the basis for promotion by NxStage of that machine functionality.

31. Based on this specification, the potential fluid balance error (*i.e.*, actual versus programmed) with System One for a 60 liter daily exchange is 3% of 60 liters, namely, plus or minus (±)1,800 milliliters. (Sixty liters is a typical daily fluid volume exchanged in contemporary CRRT.) Furthermore, System One does not alert the user or nurse to any discrepancies between actual and programmed values. A fluid imbalance of this magnitude (±1,800 milliliters) is likely to have serious clinical consequences, especially in critically ill patients with blood pressure stability problems.

32. In contrast, the current fluid accuracy specification for a 60 liter daily exchange with Prismaflex is ±300 milliliters per day. Thus, Prismaflex is up to six times more accurate than System One with respect to fluid accuracy, based on the two devices' published specifications. In addition, information about any discrepancies between actual

and programmed values within this range is continuously available to the Prismaflex user or nurse on the screen of the machine.

33. NxStage, however, has made the following misrepresentations and false or misleading statements related to System One's fluid accuracy or in comparing it favorably to that of Prisma or Prismaflex.

a. High Volume Applications

34. For the past several years, NxStage has continued to post on its website (www.nxstage.com) a white paper co-authored by NxStage's Vice President of Research and Development, Denny Treu. The white paper dated December 2007 and entitled, "CRRT Volumetric Balancing Fluid Management for the ICU" (the "Treu white paper"), states:

> While suitable in low volume use, scale-based systems have shortcomings that are exacerbated in high volume applications.
>
> * * *
>
> The System One volumetric fluid management system has been extensively tested under controlled laboratory conditions required to assess long duration/high accuracy fluid systems. The System One has demonstrated consistent accuracy during CVVHD and CVVH and is equivalent in accuracy to scale based systems.

35. On the contrary, the nature of a volumetric system is that the potential fluid balance error is a direct function of the total volume of fluid exchanged. Thus, as stated above, the potential fluid balance inaccuracy of System One is ±1,800 milliliters a day (for a 60 liter fluid exchange), six times that of Prismaflex's potential fluid balance error of ±300 milliliters a day. Since Prismaflex's daily potential fluid balance inaccuracy remains constant and is substantially lower than System One's at typical fluid exchange rates in adult patients, these statements in the Treu white paper misrepresent the two devices' published specifications and, therefore, are false and misleading. Furthermore, the implications in the Treu white paper that a

volumetric system like the System One becomes more reliable than a scale-based system like Prismaflex as fluid exchange volume increases is false and cannot be supported with clinical data.

36. Not only does this Treu white paper remain on the NxStage website, but NxStage included it in a binder provided in June 2010 to personnel at the University of Pittsburgh Medical Center during their consideration of whether to purchase Prismaflex or System One.

b. Fluid Balance Accuracy of 600 Milliliters per Day

37. In an abstract/poster entitled, "Accurate Fluid Balancing with a Novel Volumetric Control System," presented at the 2005 International CRRT Conference in San Diego and which NxStage continues to use on its website (the "2005 CRRT Poster"), NxStage states:

> [System One's] [d]aily fluid balance accuracy of 0.5 kilograms compares favorably with specifications of common scale-based systems, despite the higher therapy volumes and flow rates evaluated (e.g., Prisma 0.6 L/day, which can be impacted by room temperature changes and routine scale calibration).

38. While Prisma's daily fluid accuracy specification was ±600 milliliters a day (0.6 L/day) at the time of this initial statement in 2005, this statement became obsolete and inaccurate after the daily fluid balance specification was reduced to ±300 milliliters a day upon an FDA 510(k) clearance dated February 1, 2008. Furthermore, in the experiment upon which NxStage's poster was based, the fluid accuracy of System One was not actually tested against that of Prisma. Additionally, the System One figure was based on a laboratory experiment that did not replicate a clinical setting. Moreover, the data from this laboratory study are only preliminary and have never undergone full peer review for publication in a scientific journal, raising further questions about the data's validity.

39. Nevertheless, NxStage continues to display this poster on its website and use this poster in its promotional activities. For example, NxStage included this poster in the binder it provided to personnel at the University of Pittsburgh Medical Center in June 2010.

40. The claims made by NxStage present a level of fluid accuracy for System One's volumetric system that is significantly better than its published specification. A product's specifications and user guide reflect the most accurate and factually supportable data with respect to the device's performance parameters. If NxStage's promotional claims of fluid accuracy were in fact supported by reliable and sound data, NxStage should have amended the fluid accuracy specification and the User Guide for System One to reflect that improved accuracy. The absence of any such amendment strongly indicates that NxStage's promotional claims of better accuracy lack scientific foundation.

c. Influences on Fluid Balance Accuracy

41. At the beginning of NxStage's brochure entitled, "Every Moment Counts" (section entitled, "Technology designed to make therapy flexible and simple"), distributed at the 2009 International CRRT Conference in San Diego on February 25-27, 2009, NxStage stated:

> [T]he System One: Is highly accurate. Unlike traditional scale-based CRRT systems, volumetric control is not affected by movement, temperature, or the amount of fluid used.

42. The representation that System One is not affected by "the amount of fluid used" is false because it conflicts directly with a fundamental characteristic of all volumetric hemodialysis devices. For high fluid exchange rates, the fluid accuracy specification is ±3% for System One regardless of volumes exchanged. As higher volumes of fluid are used, therefore, dangerous inaccuracies may arise, as explained above, with potential serious clinical

consequences. Thus, NxStage's statement falsely describes and misrepresents a fundamental characteristic of System One.

43. With respect to the effect of movement and temperature, while Prismaflex's scales are very sensitive, NxStage overstates and falsely describes such effects on Prismaflex's fluid accuracy by failing to take into account Prismaflex's features designed to counteract the effects of movement and temperature on fluid accuracy. Moreover, since 2006, Prisma scales have not been affected by temperature, as they were redesigned at that time to address this issue.

44. NxStage also falsely or misleadingly describes System One's resistance to these influences. For example, because System One does not actually weigh the fluids exchanged during CRRT, the variations from programmed values cannot be tracked. Unlike gravimetric systems, these variations are not corrected on a continuous basis because System One, as a typical volumetric device, does not have a servo-feedback mechanism that compensates for potential discrepancies in fluid volumes. On the other hand, such a self-correcting mechanism is an integral and defining feature of gravimetric devices such as Prismaflex, as described previously.

45. Other examples of NxStage's false or misleading descriptions of this type include:

i. "Daily fluid balance accuracy of 0.5 kilograms compares favorably with specifications of common scale-based systems, despite the higher therapy volumes and flow rates evaluated (e.g., Prisma 0.6 L/day, **which can be impacted by room temperature changes and routine scale calibration**)." 2005 CRRT Poster still on NxStage's website (emphasis added).

ii. "Volumetric balancing, unlike scale based systems, are not sensitive to movement, temperature changes and user errors." NxStage Presentation at University of Alabama CRRT Academy, Sept. 17, 2009. (The implication that volumetric balancing is not susceptible to user error is false.)

iii. "In addition, scales are sensitive to user error, movement and other operating environment disturbances." Treu white paper.

d. NxStage's Claims That System One is Safer and More Accurate

46. In an email dated December 16, 2008 to prospective purchasers of CRRT devices at Hartford Hospital (the "Newcomb Email"), Peter Newcomb, NxStage Regional Sales Director, Critical Care, stated:

> Volumetric fluid management (exclusive to NxStage CRRT) has been the **gold standard** in hemodialysis since the early 80's. It is a **safer and more accurate means of fluid management** for your ICU patients. Additionally it provides more actual delivered therapy over the course of 24 hours of continuous treatment as compared to scale-based machines. This equates to a much higher percentage of delivered dose each day (maybe as much as 30% more), while significantly reducing the nurse's labor component associated with managing this therapy.

Emphasis added.

47. On the contrary, the predominant use of gravimetric technology for CRRT on a global basis indicates clinicians believe it is superior to volumetric technology and is a safer and more accurate means of fluid management than volumetric technology for CRRT. This view is substantiated by the fact that neither System One nor any other volumetric device has had a significant role in any major CRRT study published to date. For example, System One was not selected for use in the American Acute Renal Failure Trial Network (ATN) Trial, in which 100% of the nearly 6,000 CRRT treatments were provided by gravimetric systems. Furthermore, the first sentence of the Newcomb Email falsely implies that volumetric fluid management has been exclusive to NxStage since the early 1980s, when in fact NxStage did not offer a volumetric machine until about 20 years later.

48. NxStage Chief Executive Officer Jeffrey Burbank made the "gold standard" claim and other claims that System One is the safest in the industry in a presentation at the University of Alabama's CRRT Academy on September 17, 2009.

49. NxStage Vice President of Critical Care Mike Schrader stated that System One is the "CRRT gold standard" at the 2011 International CRRT Conference in San Diego on February 23, 2011.

50. In an email dated February 12, 2009 (the "Pettigrew Email") to several physicians and health care professionals at the University of Maryland/Baltimore Shock Trauma Hospital, Justin Pettigrew (NxStage Acute Regional Sales Manager, Mid-Atlantic Region) stated that with regard to a volumetric fluid management system, "[s]tudies show it is more accurate than scales, and thus safer for the patient."

51. In an email dated December 7, 2011 to a clinical nurse specialist for critical care at St. Joseph's Hospital Health Center in Syracuse, New York, Paul Barros (NxStage Northeast Regional Manager) stated that the "Nxstage device is a much simpler and accurate device then [*sic*] leading scale based devices **such as the one in use at St. Joe's**." Emphasis added. The "leading scale based devices . . . in use at St. Joe's" that Mr. Barros was referring to are Gambro's Prismaflex machines. Furthermore, Mr. Barros falsely referred to NxStage's System One as "the #1 CRRT device on the market." On the contrary, there are approximately twice as many Prismaflex machines in use in the United States as System One machines.

52. Controlled studies clearly have *not* demonstrated greater accuracy of volumetric systems versus gravimetric systems, and the claim that volumetric systems provide greater patient safety than gravimetric systems is completely unfounded. Moreover, the claim in the Newcomb Email that use of System One ". . . results in more actual delivered therapy . . ." has not been demonstrated by either controlled clinical studies or clinical practice. Instead, this claim is based on a single non-peer reviewed, preliminary report in which there was no control group for comparison.

53. To the contrary, nurses have recognized that System One may be systemically inaccurate and may fail to attain the physician's prescribed goals. For example, to compensate for System One's fluid inaccuracy, some nurses routinely program System One at a net fluid removal rate that is as much as 20% more than that prescribed by the physician in order to achieve the prescribed rate.

54. NxStage's repeated, false promotional claims of superior accuracy and safety of volumetric devices in general and System One in particular compared to gravimetric devices in general and Prisma or Prismaflex in particular are entirely discredited by its own Warning No. 21 in its Instructions for Use for the NxStage Cartridge Express, which states:

> 21. Weigh the patient regularly to confirm fluid balance at a frequency appropriate for the patient and the therapy duration, flow rates, and alarm conditions. Weigh the patient more frequently when using high fluid flow rates or treating low body weight patients. **Unmonitored, accumulated fluid imbalance within expected tolerances could cause patient injury. Collecting effluent dialysate and ultrafiltrate into a bag connected to the cartridge waste line and weighing the bag may be used to confirm fluid balance when treatment conditions make weighing the patient difficult.**

Emphasis added.

55. This Warning No. 21 has two important ramifications. First, it acknowledges clearly that even when System One operates within its fluid accuracy specification, clinically significant fluid imbalances can occur.

56. Second, NxStage itself acknowledges that use of scales and weighing of effluent in a bag, as done in conjunction with Prisma and Prismaflex, provide the safest and most accurate method of monitoring fluid balance and detecting imbalances, contrary to promotional statements made by NxStage's executives and sales force.

e. **False Comparisons**

57. In the slide entitled, "Accuracy: comparing apples to apples," in the binder NxStage provided in June 2010 to personnel at the University of Pittsburgh Medical Center during its consideration of whether to buy Prismaflex or System One, NxStage made the statement that fluid inaccuracy for "leading scale systems" can be as much as ±3,192 milliliters per 24 hours but only ±1,584 milliliters per 24 hours for System One "in the real world."

58. Since Gambro's Prisma and Prismaflex devices are the "leading scale systems" in the United States and since this statement was made in the context of a head-to-head comparison between Prismaflex and System One, it is apparent that the statement was targeted at Prismaflex. The assumptions made by NxStage to claim a potential fluid balance error of ±3,192 milliliters per 24 hours for Prismaflex amount to a worst-case hypothetical scenario that cannot realistically be expected to occur in actual clinical practice. Additionally, "comparing apples to apples" implies that NxStage conducted head-to-head clinical studies between System One and Prismaflex, but in fact it has not.

59. On the other hand, a maximum fluid balance error estimate of ±1,584 milliliters per 24 hours for System One represents an optimistic value because it is less than the value predicted by its published specification for a standard effluent flow rate of 2.5 liters per hour provided over 24 hours, which is 60 liters per day. As noted above, the published specification for System One clearly indicates the potential fluid balance error at such an effluent flow rate is ±1,800 milliliters per 24 hours. Furthermore, based on an effluent flow rate of 3 liters per hour, a value that is also often prescribed in the American CRRT population, the specification-based fluid balance error for System One is even greater, namely ±2,160 milliliters per 24 hours. As

mentioned previously, potential fluid balance discrepancies of this magnitude may have very serious clinical consequences in patients treated with CRRT.

2. NxStage's Claim of Reduced Anticoagulation Requirements and Increased Circuit Patency

60. Due to the clinical objective of providing CRRT on a round-the-clock basis, a crucial goal is to minimize the possibility that the patient's blood clots, thus allowing the CRRT circuit containing the blood to remain open as long as possible for continuous treatment. As a result, an anticoagulant (*i.e.*, a blood thinner) is typically added to the blood to prevent clotting and to keep the CRRT filter and circuit lines open. Because many patients requiring CRRT have a high risk of serious bleeding in the context of their critical illness, however, anticoagulation may be very problematic.

61. In the Pettigrew Email, NxStage stated that "[System One] cartridges are lasting longer than our competitor's with less anticoagulation." There is, however, no published comparison between System One's cartridges and Prismaflex's or any other competitor's cartridges with respect to length of use.

62. The Pettigrew Email went on to say that "most therapy on our device in general is without anticoagulant," thereby suggesting that use of the System One allows clinicians to avoid the clinical risks associated with anticoagulation. If this statement were factually true, it would represent a significant clinical advantage for System One over other CRRT devices.

63. The only data supporting this claim, however, are preliminary and have not been published in a peer-reviewed journal. The use of these data is extremely misleading because they originate from a single study performed at one institution and largely involved a subset of AKI patients who also suffered from liver failure. Patients with liver failure have a particularly high risk of bleeding and frequently receive no anticoagulation when treated with CRRT.

64. Furthermore, NxStage's use of these preliminary, non-peer reviewed data to promote the ability of their cartridges to be used with no anticoagulation conflicts with its own User's Guide. Specifically, on page 6-1 in the Troubleshooting section of the NxStage System One User's Guide, NxStage warns: "The risk of blood clotting in the cartridge and filter increases during long treatments, when blood flow stops, **and when no anticoagulation is used.** Give and monitor anticoagulants as your center instructs. Failure to respond to clotting may expose the blood circuit (and filter) to sustained high pressures leading to a possible filter blood leak or hemolysis. **This risk is highest in long hemodialysis treatments, especially when no anticoagulation is used.**" Emphasis added.

65. Because CRRT by its very nature involves long treatments, the Pettigrew Email promoted a clinical practice that NxStage expressly identifies as a major risk of System One in its own User's Guide.

66. Similarly, in the Newcomb Email, NxStage stated, "Many of our customers will verify that our blood cartridges last longer while requiring less anticoagulant. In fact, most of our customers have success running CRRT without any anticoagulation at all." No objective data accompanied this anecdotal statement.

3. <u>System One's Claim of Reduced Nursing Workload Compared to Prismaflex</u>

67. NxStage has made a number of unsubstantiated and false or misleading statements that System One requires less nursing labor time than Prismaflex. These statements are based on System One's method of effluent disposal, which does not involve bags that need to be emptied or replaced but rather drains fluid through a tubing line into a sink or toilet. As noted above and below, NxStage's own Warning No. 21 acknowledges that this method of effluent disposal may pose serious safety risks.

68. In the Newcomb Email, NxStage stated:

> Volumetric fluid management (exclusive to NxStage CRRT) has been the gold standard in hemodialysis since the early 80's. It is a safer and more accurate means of fluid management for your ICU patients. Additionally it provides more actual delivered therapy over the course of 24 hours of continuous treatment as compared to scale-based machines. This equates to a much higher percentage of delivered dose each day (maybe as much as 30% more), **while significantly reducing the nurse's labor component associated with managing this therapy**.

Emphasis added.

69. In an email dated November 20, 2008 to a nurse educator at West Los Angeles VA Hospital, Mike Schrader (NxStage Vice President of Critical Care) stated:

> As we discussed, the magic of our system (**that eliminates the work for the ICU nurse**) is the NxStage System volumetric fluid management system; instead of weighing fluids (like the labor intensive scale based technology) the NSO [NxStage System One] measures the fluid (allowing the effluent to go right down the drain, instead of into a waste bag on a scale that needs to be emptied on an hourly basis).

Emphasis added. Schrader also stated that System One allows ICU nurses "... to use a less labor intensive device..." and that the device "...eliminates a lot of unnecessary work for the bedside ICU nurse." These claims are not supported by any publications (peer reviewed or non-peer reviewed) or any other source of credible, objective data and, therefore, cannot be substantiated.

70. On pages 1-2 of the Treu white paper, NxStage states on its website:

> Scale capacity limitations require frequent solution and effluent bag changes by an already overloaded nursing staff.
>
> * * *
>
> The NxStage System One enables the ICU to meet their goals of economically delivering more intensive renal replacement therapies while reducing the strain on overburdened critical care staff and resources, thereby allowing nurses to spend more time with their patients.

71. In the Pettigrew Email, NxStage touted as a "unique" feature of System One, "Considerable reduction in nurse workload while managing the therapy."

72. In the binder NxStage provided to personnel at the University of Pittsburgh Medical Center in June 2010, NxStage stated:

a. "ICU nurses now have more time to spend with their patients and less time doing traditional scale based CRRT machine related responsibilities."

b. "There will be less CRRT machine related work for the ICU nurses."

c. The ICU incremental labor time is 0.5 hours for the NxStage device compared to 2 hrs for "Gambro."

73. NxStage's statements that System One reduces ICU nurse workload and time compared to Prisma or Prismaflex are unsubstantiated and misleading. There are no published studies in which System One has been contemporaneously compared to gravimetric systems, and no published study has demonstrated that use of System One reduces nurse workload and time. Moreover, NxStage has not performed a systematic analysis of the proportion of a typical ICU nurse's overall effort spent managing CRRT in relation to other patient-related responsibilities.

74. NxStage's claims of lower nurse workload also assume that a patient's needs remain stable throughout his or her entire course of CRRT, which on average lasts approximately six days. On the contrary, however, an AKI patient is typically very unstable, and the treating physician continually modifies his or her clinical management to address changes in the patient's condition. Consequently, nurses may have to manipulate the System One fairly regularly as the CRRT prescription changes. Accordingly, any difference in nurse workload or time spent administering therapy with System One, on the one hand, and with Prisma or Prismaflex, on the other hand, is likely to be insignificant.

75. Additionally, as described above, NxStage itself has issued Warning No. 21 in its Instructions for Use for the NxStage Cartridge Express stating that safe delivery of therapy by way of System One may require frequent weighing of the patient and/or the effluent to monitor

fluid balance. Thus, use of System One in this manner certainly does not reduce nurse workload compared to use of Prisma or Prismaflex. In fact, since Prisma and Prismaflex are equipped with scales and bags for the express purpose of collecting and weighing effluent and since System One has neither, use of System One in this manner actually increases nurse workload compared to Prisma and Prismaflex.

4. NxStage's Promotion of Therapy with System One as the Equivalent of Prismaflex's CVVHDF

76. Continuous Veno-Venous Hemodiafiltration ("CVVHDF") is the most commonly prescribed CRRT modality in the United States and globally. In fact, CVVHDF was the sole modality prescribed in the two largest clinical studies performed in the AKI population, the ATN Trial and the Randomized Evaluation of Normal versus Augmented Level (RENAL) Replacement Therapy Trial. As noted previously, CVVHDF entails use of both dialysate and replacement fluid and is a combination of hemodialysis and hemofiltration. CVVHDF, however, has not been cleared by the FDA as a modality that can be performed by System One, which can perform only continuous hemodialysis (CVVHD) or continuous hemofiltration (CVVH).

77. In order for System One to deliver CVVHDF therapy, an additional external pump is required for replacement fluid delivery. The large volume of fluid infused by the external pump (which may have substantial variances from prescribed rates) is not processed automatically by System One's fluid balance control system. Moreover, the operation of such an external pump is not linked to the operation of the System One pumps and, therefore, can lead to discordance between the external pump and the System One blood/fluid pumps.

78. Nevertheless, in an attempt to overcome such limitations in order to persuade hospitals to purchase System One for CRRT, NxStage has made false and misleading statements

that CVVHD, as provided by System One, is clinically equivalent to CVVHDF. For example, NxStage made such statements (a) at the University of Pittsburgh CRRT Conference in Fall 2010, (b) to ICU staff at the University of Alabama Hospital on September 17, 2009, and (c) during a demonstration to nurses and physicians at Tampa General Hospital in 2006.

79. In comparison to CVVH and especially CVVHDF, very little information regarding actual patient outcomes after treatment with CVVHD can be found in the published literature. In fact, to support its CVVHD-CVVHDF equivalence claim, NxStage has relied on unpublished, non-peer reviewed data found in an abstract entitled, "Improved Diffusive Solute Clearances with Novel CRRT Equipment and Dialyzer Design," which it presented at the 2006 International CRRT Conference in San Diego.

80. This study, which compared CVVHD as provided by System One to CVVHDF as provided by Prisma, violated a number of basic scientific principles. These violations included (a) failure to employ a control group; (b) comparing a System One *laboratory* experiment in 2005 to a Prisma *clinical* study published in 1999; (c) use of a blood flow rate of 250 milliliters per minute for the System One laboratory experiment versus 150 milliliters per minute in the Prisma study; (d) use of a System One filter with a membrane surface area that was 60% greater than the Prisma filter; (e) comparing System One to Prisma when Prismaflex was the most relevant comparator; and (f) referring to "pharmacy compounding or contamination risk" for replacement fluids when the vast majority of such fluids in the United States are no longer pharmacy compounded, especially after the introduction of Prismasol by Gambro in 2008. Moreover, the study only focused on one aspect of CRRT (*i.e.*, toxin removal) and did not report actual patient outcomes, diminishing the clinical equivalence claim even further. Finally, it should be noted that one of the authors of this abstract was a NxStage employee (Goetz

Friederichs), raising questions about the objectivity of these preliminary data that were not peer reviewed.

FIRST CLAIM FOR RELIEF (Lanham Act)

81. Gambro repeats and realleges Paragraphs 1-80.

82. In connection with NxStage's System One and in commercial advertising or promotion, NxStage has used in commerce false or misleading descriptions of fact and false or misleading representations of fact that misrepresent the nature, characteristics, or qualities of (a) NxStage's System One, (b) of gravimetric CRRT devices, in general, and (c) of Gambro's Prisma and Prismaflex, in particular, all in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

83. NxStage's false or misleading advertising and promotion of System One alone or in comparison to Prisma and Prismaflex have caused and, unless enjoined, will continue to cause: (a) confusion, deception, and mistake among hospital customers of CRRT devices whose decisions as to competing CRRT devices are likely to be affected by considerations of fluid accuracy, safety, anticoagulation requirements, nurse workload, and CVVHDF equivalency; (b) Gambro to suffer loss of goodwill, sales, and profits of millions of dollars; (c) NxStage to unfairly enjoy sales and profits to which it is not entitled; and (d) irreparable harm to Gambro.

84. In particular, NxStage's false advertising and promotions have caused Gambro to lose sales and customers, including without limitation Massachusetts General Hospital, Brigham & Women's Hospital, Baystate Medical Center, Boston Medical Center, University of Massachusetts Memorial Medical Center, the Lahey Clinic, Thomas Jefferson University Hospital, The Johns Hopkins Hospital, UCLA Medical Center, and Hermann Memorial Medical Center.

85. In the case of NxStage's misleading descriptions or representations of fact, customers have been actually misled by such statements.

86. By its conduct in violation of the Lanham Act, NxStage has unfairly competed with Gambro and continues to compete unfairly with Gambro.

87. NxStage has willfully and deliberately violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), warranting an award of treble damages and attorney's fees under 15 U.S.C. § 1117(a) as this is an exceptional case.

88. Gambro has no adequate remedy at law for NxStage's continuing acts of false advertising and promotions.

SECOND CLAIM FOR RELIEF (Intentional Interference with Contractual Relations)

89. Gambro repeats and realleges Paragraphs 1-88.

90. NxStage has known that many of the persons to whom it has made false and misleading statements about System One, Prisma, and Prismaflex have been or are customers of Gambro because a number of NxStage sales personnel have been former Gambro sales personnel and because during sales visits to hospital ICUs throughout the United States, NxStage has learned which hospitals use or used Prisma or Prismaflex. At the time NxStage made such false and misleading statements to Gambro's customers, NxStage knew such customers owned and were operating Prisma and/or Prismaflex devices and were ordering and purchasing from Gambro, either through purchase orders or a supply contract, a number of supporting products used in connection with Prisma and Prismaflex, such as replacement and dialysate fluids, hemofilter sets, and equipment parts.

91. By making such false and misleading statements about System One, Prisma, and Prismaflex to Gambro's customers, NxStage intentionally and improperly caused some of

Gambro's customers, including without limitation Thomas Jefferson University Hospital, The Johns Hopkins Hospital, UCLA Medical Center, and Hermann Memorial Medical Center, to discontinue using Prisma or Prismaflex devices and their supporting products, to discontinue ordering supporting products from Gambro under supply contracts still in effect, and to purchase System One devices and supporting products instead.

92. By making such false and misleading statements about System One, Prisma, and Prismaflex to Gambro's customers and by violating Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), NxStage has tortiously and intentionally interfered with and continues to tortiously and intentionally interfere with Gambro's contractual relationships with its customers, all with an improper motive or purpose and by improper means.

93. As a result of NxStage's improper, tortious, and intentional interference with Gambro's customers, Gambro has been and will continue to be damaged.

94. Gambro has no adequate remedy at law for NxStage's continuing acts of improper, tortious, and intentional interference with its contractual relationships with its customers.

THIRD CLAIM FOR RELIEF (Intentional Interference with Advantageous Relations)

95. Gambro repeats and realleges Paragraphs 1-94.

96. Gambro derives revenue from repeat business from satisfied customers that order new Prismaflex devices to replace older ones or to add to their fleet and from new orders of Prismaflex devices from new customers.

97. Gambro also derives revenue from sales of supporting products used in connection with Prisma and Prismaflex, such as replacement and dialysate fluids, hemofilter sets, and equipment parts.

98. As a result, Gambro enjoys an advantageous relationship with its past, present, and prospective customers that facilitates continuing and future sales of Prismaflex and supporting products used in connection with Prisma and Prismaflex.

99. NxStage has known that many of the persons to whom it has made false and misleading statements about System One, Prisma, and Prismaflex are past, present, or prospective customers of Gambro because a number of NxStage sales personnel have been former Gambro sales personnel and because during sales visits to hospital ICUs throughout the United States, NxStage has learned which hospitals use or used Prisma or Prismaflex or were considering using Prisma or Prismaflex.

100. By making false and misleading statements about System One, Prisma, and Prismaflex to persons who NxStage knew were Gambro's past, present, and prospective customers and by violating Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), NxStage has knowingly and intentionally tortiously interfered with and continues to knowingly and intentionally tortiously interfere with Gambro's advantageous relationships with such customers, all with an improper motive or purpose and by improper means.

101. As a result of NxStage's improper and tortious interference with Gambro's advantageous relationships, Gambro has been and will continue to be damaged.

102. Gambro has no adequate remedy at law for NxStage's continuing acts of tortious interference with its advantageous relationships.

FOURTH CLAIM FOR RELIEF (Violation of Mass. G.L. c. 93A)

103. Gambro repeats and realleges Paragraphs 1-102.

104. At all times material to this action, Gambro has been a person engaged in the conduct of trade or commerce, within the meaning of Massachusetts G.L. c. 93A, in the Commonwealth of Massachusetts and throughout the United States.

105. At all times material to this action, NxStage has been a person engaged in the conduct of trade or commerce, within the meaning of Massachusetts G.L. c. 93A, in the Commonwealth of Massachusetts and throughout the United States.

106. NxStage and Gambro have been business competitors with respect to CRRT devices.

107. The foregoing actions and conduct of NxStage, including violating the Lanham Act, falsely advertising and promoting System One, using in commerce false or misleading descriptions of fact and false or misleading representations of fact that misrepresent the nature, characteristics, or qualities of NxStage's System One and Gambro's Prisma and Prismaflex, and tortiously and intentionally interfering with Gambro's contractual relationships and advantageous relationships with its past, present, and prospective customers, occurred primarily and substantially within the Commonwealth of Massachusetts or originated, emanated, or were directed from or approved at NxStage's headquarters in Lawrence, Massachusetts, including through the training of its sales force. In particular, NxStage has engaged in such conduct and actions in successfully procuring sales of System One and its supporting products in Massachusetts to Massachusetts General Hospital, Brigham & Women's Hospital, Baystate Medical Center, Boston Medical Center, University of Massachusetts Memorial Medical Center, and the Lahey Clinic.

108. Through such actions and conduct, NxStage has knowingly and willfully engaged in conduct that violates Massachusetts G.L. c. 93A, that is immoral, unethical, oppressive, and unscrupulous, and that offends public policy.

109. By such actions and conduct, NxStage has engaged in unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce in violation of Mass. G.L. c. 93A, §§ 2 and 11.

110. As a direct and proximate result of NxStage's actions and conduct, Gambro has suffered and continues to suffer losses of millions of dollars.

111. Gambro has no adequate remedy at law for NxStage's continuing violations of Mass. G.L. c. 93A.

TRIAL BY JURY

Gambro demands trial by jury on all claims and issues triable by a jury.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Gambro Renal Products, Inc. prays for:

1. Compensatory damages.

2. Disgorgement and recovery of NxStage's profits from the sale of System One devices and supporting products pursuant to 15 U.S.C. § 1117(a).

3. Three times Gambro's actual damages pursuant to 15 U.S.C. § 1117(a) and two or three times Gambro's actual damages pursuant to Mass. G.L. c. 93A, § 11.

4. Attorney's fees pursuant to 15 U.S.C. § 1117(a), as an exceptional case, and pursuant to Mass. G.L. c. 93A, § 11.

5. Preliminary and permanent equitable relief, pursuant to 15 U.S.C. § 1116 (a), Mass. G.L. c. 93A, § 11, and the Court's equitable powers, enjoining and prohibiting NxStage and its officers, directors, employees, agents, and representatives and all persons in active concert or participation with them from: (a) mentioning Gambro, any Gambro product, or any CRRT gravimetric device in any of NxStage's oral or written advertising, promotions, marketing, sales efforts, brochures, or websites or at any medical or industry conferences or continuing medical education programs; (b) using in commerce false or misleading descriptions of fact and false or misleading representations of fact that misrepresent the nature, characteristics, or qualities of NxStage's System One, volumetric devices, Gambro's Prisma or Prismaflex, and gravimetric devices; and (c) interfering with Gambro's contractual relationships and advantageous relationships with its past, present, and prospective customers.

6. Preliminary and permanent equitable relief, pursuant to 15 U.S.C. § 1116 (a), Mass. G.L. c. 93A, § 11, and the Court's equitable powers, enjoining and directing NxStage to publish on its website and in all periodicals in which it has advertised within the past year a

retraction of its false or misleading descriptions of fact and false or misleading representations of fact that misrepresent the nature, characteristics, or qualities of NxStage's System One, volumetric devices, Gambro's Prisma or Prismaflex, or gravimetric devices.

7. Interest.

8. Costs.

9. Such other and further relief as the Court deems just and proper.

Dated: February 28, 2012

PLAINTIFF,
GAMBRO RENAL PRODUCTS, INC.

By its attorneys,

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